

Notice of Allowability

Application No.

10/621,229

Examiner

Jennifer Kim

Applicant(s)

IBANEZ, JUAN JOSE LEGARDA

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/20/2007 & 12/4/2007.
2. ☒ The allowed claim(s) is/are 59, 61-68, 70 and 71 (renumbered as 1, 2-9, 10 and 11 respectively).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 3/20/2007
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____.

Jennifer Kim
Primary Examiner
Art Unit 1617

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. John McDonald on December 4, 2007.

The application has been amended as follows:

In the Claims:

Claim 59 has been **replaced** with:

"A method to reduce a desire to drink alcohol in a patient having the desire to drink alcohol comprising administering an effective amount of flumazenil to the patient, wherein the flumazenil is administered sequentially in doses between about 0.1 and 0.3mg of flumazenil at time intervals between about 1 and 15 minutes, wherein the amount of flumazenil is effective to reduce the desire to drink alcohol in the patient, and the effective amount of flumazenil is between about 1.5 and 2.5mg/day."

Claim 60 has been **canceled** without prejudice.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious the claimed method to reduce a desire to drink alcohol in a patient having the desire to drink alcohol comprising administering an effective amount of flumazenil to the patient, wherein the flumazenil is administered sequentially in doses between about 0.1 and 0.3mg of flumazenil at time intervals between about 1 and 15 minutes, wherein the amount of flumazenil is effective to reduce the desire to drink alcohol in the patient, and the effective amount of flumazenil is between about 1.5 and 2.5mg/day.

The cited prior art of record, Soderpalm et al. teaches that benzodiazepines acting on GABA receptors, may facilitate ethanol intake by increasing ethanol's taste hedonic properties. It also teaches the effect of flumazenil on midazolam-induced enhancement of alcohol taste reactivity. (page 217, left-hand column). The amount

employed in this reference is very high (10mg/kg), compared to instantly claimed amounts (between 1.5 and 2.5mg/day). Moreover, it teaches that the administration of flumazenil alone exerted no significant effect on alcohol taste reactivity in comparison to a vehicle. (page 219, left hand side, first paragraph). Therefore, there is no motivation for employment of low dosages as claimed (between 1.5 and 2.5mg/day) with specific dosing intervals for the treatment of reducing desire to drink alcohol in a patient having the desire to drink alcohol because there is no expectation of success from this reference which teaches that there is no significant effect on alcohol taste reactivity in employment at higher dosages (10mg/kg) of flumazenil.

The prior art, June et al. of record teaches BDZ inverse agonist can attenuate motivated behavior for EtOH reinforcement over a prolonged time course may provide a possible therapeutic approach to reducing EtOH consumption associated with alcoholism. However, the specific BDZ receptor antagonist, flumazenil, is not effective in decrease in EtOH intake when administered alone. (see result on Fig. 5). Therefore, there is no motivation of employment of Flumazenil for the reduction of alcohol desire in a patient having desire to drink alcohol because there is no expectation of success in reducing EtOH consumption as shown by June et al. Moreover, there is no teaching or suggestion of the specific dosages with the specific dosing intervals as claimed in the instant Application in this reference.

The prior art of record, Buck et al. of record teach the ability of flumazenil (RO-151788) to reverse neuronal and behavior manifestation of ethanol tolerance and

dependence. Buck et al. also teach that ethanol consumption in vehicle-injected and flumazenil-treated mice did not differ in the 14 hour between administration of vehicle or flumazenil and withdrawal from ethanol. (page 987, left-hand side). Therefore, there is no motivation of employment of Flumazenil for the reduction of alcohol desire in a patient having desire to drink alcohol because there is no expectation of success in reducing ethanol consumption as taught by Buck et al. Moreover, there is no teaching or suggestion of the specific dosages with the specific dosing intervals as claimed in the instant Application in this reference.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from

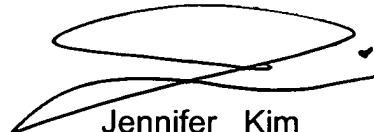
Application/Control Number:
10/621,229
Art Unit: 1617

Page 6

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim
Primary Examiner
Art Unit 1617

Jmk
December 21, 2007